

**Notice of Allowability**

Application No.

09/753,139

Applicant(s)

QUIRK ET AL.

Examiner

Art Unit

Malgorzata A. Walicka

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 08/08/05.
2. ☒ The allowed claim(s) is/are 1,8 and 15-23.
3. ☒ The drawings filed on 20 December 2000 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some\* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
- \* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |  |   |
|--|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892)   | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)           |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 6. <input type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date _____ |
| 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br>Paper No./Mail Date <u>08/18/05</u> | 7. <input type="checkbox"/> Examiner's Amendment/Comment                              |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material                               | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance  |
|  | 9. <input type="checkbox"/> Other _____   |

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The Amendment and Response filed August 8, 2005 are acknowledged. Claims 2-7, 9-14 and 18-23 have been cancelled. Claims 1, 8 and 15-17 are pending and under examination.

## **Detailed Office Action**

### **1. Restriction/election**

The restriction/election issues were clarified in the Office Action of June 6, 2005 and during the interview of July 26, 2005. The currently amended claim 8 directed to the process of using the patentable product, previously withdrawn from consideration as a result of a restriction requirement, is the subject to being rejoined and fully examined for patentability under 37 CFR 1.104.

### **2. Objections**

#### *2.1. Specification*

##### Objection withdrawal

Objection to the specification because of typographic errors is withdrawn, because the errors have been corrected.

#### *2.2. Claims*

##### Objection withdrawal

Objection to the claims for lack of expanding of the abbreviations is withdrawn, because the claims have been amended.

### **3. Rejections**

#### **3.1. 35 USC section 112, first paragraph**

##### *3.1.1. Lack of written description*

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Claims 1-3, 7, 15-19 and 23 were rejected under 35 U.S.C. 112, first paragraph, in the final rejection of June 6, 2005. Rejection of claims 2-3, 7, 18-19 and 23 is moot because the claims have been cancelled.

Rejection of claims 1, 15-17 is withdrawn, because the claims have been amended.

### *3.1.2. Scope of enablement*

Claims 1- 3, 7 and 15-23 were rejected in the final rejection of June 6, 2005. Rejection of claims 2-3, 7, 18-19 and 23 is moot because the claims have been cancelled.

Rejection of claims 1, 15-17 is withdrawn, because the claims have been amended.

## **4. Examiner's amendment**

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Please amend the claims 1, 8, 15 and 17 as follows:

1. A metalloproteinase regulator comprising a 2-amino-4-fluorophenol N,N,O triacetic acid zinc chelator covalently attached to the N-terminus of [and] a TIMP-derived peptide consisting essentially of SEQ ID NO:8.
8. A method of treating chronic or acute wounds comprising administering a metalloproteinase regulator comprising a 2-amino-4-fluorophenol N,N,O triacetic acid zinc chelator covalently attached to the N-terminus of [and] a TIMP-derived peptide consisting essentially of SEQ ID NO:8.
15. A composition comprising a pharmaceutically acceptable carrier and a metalloproteinase regulator, wherein the metalloproteinase regulator comprises a 2-amino-4-fluorophenol N,N,O triacetic

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acid zinc chelator covalently attached to the N-terminus of [and] a TIMP-derived peptide consisting essentially of SEQ ID NO:8.

17. The composition of Claim 15, wherein the composition is in the form of a lotion, ointment, cream, gel, stick, spray, paste, mousse, solution, dispersion, emulsion, solid[, and] or liposome.

Authorization for this examiner's amendment was given in a telephone interview with Robin Chadwick on August 17, 2005.

#### 5. Allowance

Claims 1, 8 and 15-17 are allowed. The following is the examiner's reason for allowance. Applicants disclose an inhibitor of human matrix metalloprotease MMP-9, which has a potential clinical application in controlling wound healing, rheumatoid arthritis, osteoporosis, gastric ulcers and tumor metastasis. The invention is non obvious and free of prior art. Applicants new idea consist of blocking the active center of metalloprotease by the peptide of SEQ ID NO:8 and at the same time chelating zinc atoms necessary for activity of the metalloprotease by 2-amino-4-fluorophenol N,N,O triacetic acid brought to the vicinity of the active center by SEQ ID NO:8. The claimed chemical compound consists of 2-amino-4-fluorophenol N,N,O triacetic acid zinc chelator and a polypeptide sequence consisting essentially of SEQ ID NO:8 wherein the covalent linkage brings the chelator into close proximity to the  $Zn^{++}$  of the MMP-9 to provide increased inhibitory effect. The language "consisting essentially of" is, for the purpose of searching and applying prior art, construed as equivalent to "comprising"; see MPEP 2111.03 "Transitional Phrases". This language has support on page 14, lines 9-10 of the instant specification, where Applicants state that the novel synthetic peptides of the invention comprise relatively short stretches of amino acids that correspond to the TIMP/MMP-9 binding domain, and in original claim 6 in which these peptides are defined as specifically including SEQ ID NO:8

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Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Malgorzata A. Walicka whose telephone number is (571) 272-0944. The examiner can normally be reached on Monday-Friday from 10:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Art Unit 1652  
Patent Examiner

  
**REBECCA E. PROUTY**  
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